IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KD, a minor, by his parent and natural guardian, Kenneth Dieffenbach, and KENNETH DIEFFENBACH, in his own right	:	
Plaintiff,	:	
v.	:	Civ. No. 07-515-GMS-MPT
UNITED STATES OF AMERICA,	:	
Defendant.	:	

MEMORANDUM ORDER

I. INTRODUCTION

Presently before the court is defendant the United States' motion for a protective order covering documents generated through peer review at the National Heart, Lung and Blood Institute ("NHLBI") within the National Institutes of Health ("NIH").[1] Plaintiff seeks disclosure of documents related to ongoing monitoring of the NIH research protocol in which he participated. The United States asserts these documents are privileged under the Maryland medical peer review statute, the federal self-critical analysis privilege, and federal common law. The parties completed briefing on this issue on April 9, 2010. For the reasons below, the United States' motion for a protective order is GRANTED in part and DENIED in part.

[1] D.I. 48.

II. BACKGROUND

A. Plaintiff

According to medical records produced by plaintiff's counsel, plaintiff was born on September 13, 1990, and was diagnosed shortly thereafter with a heart murmur.[2] At the age of 5, he was admitted to the Children's Hospital of Philadelphia for observation and evaluation of syncope, a loss of consciousness caused by diminished cerebral blood flow.[3] Following testing, plaintiff was diagnosed with hypertrophic cardiomyopathy, a genetic condition with a substantial risk of sudden cardiac death, especially in children.[4] Dr. Bhat, a pediatric cardiologist at Children's Hospital, referred plaintiff to NIH for enrollment in a NHLBI research protocol studying whether implanting pacemakers in children with this condition would improve their outcomes.[5]

Dr. Lameh Fananapazir, the Principal Investigator of the NHLBI study, implanted a pacemaker in plaintiff on December 13, 1995.[6] Plaintiff returned to NIH periodically over the next several years for monitoring, but eventually sought medical care elsewhere, primarily at Children's Hospital of Philadelphia and Boston Children's Hospital.[7] In September 2003, following a syncopal episode, the pacemaker was removed and a dual chamber defibrillator was implanted at Children's Hospital of Philadelphia.[8] Plaintiff underwent further cardiac surgery at Boston Children's Hospital

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[2] D.I. 49 at 2.
[3] *Id.* at 2-3.
[4] *Id.* at 3.
[5] *Id.*
[6] *Id.*
[7] *Id.*; D.I. 50 at 2.
[8] D.I. 49 at 3.

in May 2004.[9]

Plaintiff claims his parents were lied to and frightened into giving their consent to enroll plaintiff in the NHLBI study. Plaintiff also claims the United States violated rules and regulations that were in place to protect research subjects from unethical conduct and harm. Plaintiff alleges that his condition is significantly worse and that he is at a greater risk of death due to these violations.

B. NIH

The NIH, a part of the U.S. Department of Health and Human Services, is the primary federal agency for conducting and supporting medical research. It is composed of 27 institutes and centers, among them the NHLBI.[10] The NHLBI provides "global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and to enhance the health of all individuals."[11] NHLBI researchers conduct clinical studies with patients who have diseases of the heart and blood vessels, lungs, blood cells and bone marrow, or cholesterol at the NIH Clinical Center in Bethesda, Maryland.[12] Unlike most hospitals, the Clinical Center does not routinely provide standard diagnostic and treatment services. Instead, patients are admitted because they have a illness being studied.

Clinical research at the NIH is conducted by a Principal Investigator (in this case Dr. Fananapazir), according to a plan known as a protocol.[13] These protocols are

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[9] *Id.*
[10] D.I. 49-1 at ¶ 3.
[11] *Id.*
[12] *Id.* at ¶ 4.
[13] *Id.* at ¶ 8.

designed to safeguard the participants' health and to answer specific research questions.[14] Each research study at the NIH Clinical Center must be approved and monitored by an Institutional Review Board ("IRB").[15] IRBs are independent committees mandated by federal regulation and consisting of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of participants are protected.[16] The NHLBI IRB reviews NHLBI research protocols at least annually.[17]

Principal Investigators are required to submit a general description of a data and safety monitoring plan with research protocols.[18] All clinical trials require such monitoring, which is distinct from the requirement for study review and approval by an IRB.[19] Data and safety monitoring may be conducted by the Institute staff or by a separate Data Safety Monitoring Board ("DSMB") composed of clinical trial experts, biostatisticians, physicians and others knowledgeable about the disease or treatment under study.[20] At the NHLBI, the DSMB reviews clinical trial progress and safety, and advises the Institute Director whether to continue, modify, or terminate a trial.[21] The NIH policy for Data and Safety Monitoring provides that confidentiality must be maintained during all phases of the trial, including monitoring, preparation of interim results, review,

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[14] *Id.*
[15] *Id.* at ¶ 9.
[16] *Id.*
[17] *Id.* at ¶ 10.
[18] *Id.* at ¶ 11.
[19] *Id.*; NIH Policy for Data and Safety Monitoring (June 10, 1998), *at* http://grants.nih.gov/grants/guide/notice-files/not98-084.html.
[20] *Id.*
[21] *Id.* at ¶ 12.

and response to monitoring recommendations.[22]

III. DISCUSSION

A. Applicable Law

This court must first determine whether state or federal privilege law applies to the materials at issue. Assertions of privilege in federal cases are governed by Federal Rule of Evidence 501. Rule 501 provides:

> Except as otherwise required by the Constitution of the United States or provided by Act of congress or in rules prescribed by the Supreme Court pursuant to statutory authority, the privilege of a witness, person, government, State, or political subdivision thereof shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness, person, government, State, or political subdivision thereof shall be determined in accordance with State law.

The United States argues that state law "supplies the rule of decision" here because courts are directed to state law in determining negligence under the Federal Tort Claims Act ("FTCA").[23] This reasoning seems to comport with the plain language of Rule 501, and some courts have adopted it.[24] These cases, however, fail to distinguish between situations in which state law operates of its own force (such as federal cases

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[22] *Id.*; NIH Policy for Data and Safety Monitoring.

[23] D.I. 49 at 6. The FTCA is codified at 28 U.S.C. § 2671 *et seq.*, and provides that "[t]he United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances." 28 U.S.C. § 2674. Absent the FTCA, this claim would have been brought in Maryland state court under Maryland law. Hence, Maryland law controls whether the United States can be held liable for negligence.

[24] *See, e.g., MacDonald v. United States*, 767 F. Supp. 1295, 1298 n.3 (M.D. Pa. 1991); *Johns v. United States*, No. CIV. A. 96-1058, 1997 WL 695608, at *2 (E.D. La. Nov. 6, 1997); *Oslund v. United States*, 128 F.R.D. 110, 112-13 (D. Minn. 1989).

based on diversity jurisdiction), and those in which state law operates through incorporation or adoption in federal law (as in cases such as this one arising under the FTCA).[25] The Senate-House Conference, in adopting Rule 501, addressed this very issue, stating:

> In nondiversity jurisdiction civil cases, federal privilege law will generally apply. In those situations where a federal court adopts or incorporates state law to fill interstices or gaps in federal statutory phrases, the court generally will apply federal privilege law . . . . When a federal court chooses to absorb state law, it is applying the state law as a matter of federal common law. Thus, state law does not supply the rule of decision (even though the federal court may apply a rule derived from state decisions), and state privilege law would not apply.[26]

Examination of the legislative history of Rule 501 thus reveals that Congress intended federal courts to apply state privilege law only where state substantive law operates of its own force.[27] Because Maryland negligence law operates in this case only by incorporation into the FTCA, this court will evaluate defendant's assertion of privilege under federal common law.

B. Medical Peer Review under Federal Common Law

Under Federal Rule of Civil Procedure 26(b)(1), any information that is not privileged is discoverable if it is relevant to the action or reasonably calculated to lead to

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[25] *See Moor v. County of Alameda*, 411 U.S. 693, 701 (1973) ("It is, of course, not uncommon for Congress to direct that state law be used to fill the interstices of federal law."); *Id.* at 701 n.11 ("A ready example of such federal adoption of state law is to be found in the Federal Tort Claims Act under which the United States is made liable for certain torts of its employees in accordance with relevant state law.").

[26] Conf.Rep. No. 1597, 93d Cong., 2d Sess. (1974), *reprinted in* 1974 U.S.C.C.A.N. 7098, 7101.

[27] For a more thorough analysis of the legislative history behind Rule 501, *see Young v. United States*, 149 F.R.D. 199, 201-04 (S.D. Cal. 1993), the relevant portion of which this court adopts.

admissible evidence. The party asserting a privilege bears the burden of proving its existence and applicability.[28] In federal question cases, Federal Rule of Evidence 501 directs that, unless otherwise required by the Constitution, an act of Congress, or in rules prescribed by the Supreme Court pursuant to statutory authority, privileges "shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience." Rule 501 thus provides federal courts with a measure of flexibility in crafting privilege law.

This flexibility notwithstanding, courts have long disfavored the recognition of privileges in federal practice in view of the broad discovery permitted under federal rules.[29] Privileges are therefore "strictly construed" because they contravene the fundamental principle that "the public . . . has a right to every man's evidence."[30] For a privilege to be added to the federal common law, then, it must promote "sufficiently important interests to outweigh the need for probative evidence."[31] Courts are especially reluctant to recognize a privilege "where it appears that Congress has considered the relevant competing concerns but has not provided the privilege itself."[32] Courts conduct this analysis on a case-by-case basis, taking into account both the

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[28] *In re Grand Jury Investigation*, 918 F.2d 374, 385 n.15 (3d Cir. 1990) (citing *In re Bevill, Bressler & Schulman Asset Mgmt. Corp.*, 805 F.2d 120, 124 (3d Cir.1986) and *In re Grand Jury Empaneled Feb. 14, 1978*, 603 F.2d 469, 474 (3d Cir.1979)).

[29] *See, e.g., Wei v. Bodner*, 127 F.R.D. 91, 96 (D.N.J. 1989) ("Privileges are disfavored in federal practice.") (citing *Herbert v. Lando*, 441 U.S. 153 (1979)).

[30] *Univ. of Pa. v. EEOC*, 493 U.S. 182, 189 (1990) (citations omitted); *see also United States v. Nixon*, 418 U.S. 683, 710 (1974) ("[Privileges] are not lightly created nor expansively construed for they are in derogation of the search for truth.").

[31] *Jaffee v. Redmond*, 518 U.S. 1, 9 (1996) (quoting *Trammel v. United States*, 445 U.S. 40, 51 (1980)).

[32] *Univ. of Pa.*, 493 U.S. at 189.

public and private interests that the privilege serves, as well as the evidentiary benefit that would result if the privilege were denied.[33]

Although Maryland privilege law does not control here, this court must nevertheless consider the public policy behind its privilege in determining whether to recognize a corresponding federal privilege.[34] Indeed, "[a] strong policy of comity between state and federal sovereignties impels federal courts to recognize state privileges where this can be accomplished at no substantial cost to federal substantive and procedural policy."[35] This court, however, is not required to apply state privileges exactly as a state court would, unless it considers such treatment necessary and appropriate as a matter of federal common law.[36] A federal court may analogize to the state privilege and what a state court would do to guide the development of federal common law.[37]

A privilege for medical peer review materials has not been recognized in this circuit. While some courts outside this circuit have applied a privilege to these materials,[38] the balance of authority weighs against recognition.[39] Despite this

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[33] *Tucker v. United* States, 143 F. Supp. 2d 619, 626 (S.D. W. Va. 2001) (citing *Jaffee*, 518 U.S. at 8).

[34] *See Riley v. City of Chester*, 612 F.2d 708, 715 (3d. Cir. 1979).

[35] *Pearson v. Miller*, 211 F.3d 57, 67 (3d. Cir. 2000) (quoting *Mem'l Hosp. for McHenry County v. Shadur*, 664 F.2d 1058, 1061 (7th Cir. 1981)).

[36] *See Wei*, 127 F.R.D. at 95 (D.N.J. 1989).

[37] *Id.* (citing *Wm. T. Thompson Co. v. Gen. Nutrition Corp., Inc.*, 671 F.2d 100, 104 (3d Cir.1982)).

[38] *See Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249 (D.D.C. 1970) (extending qualified privilege to the minutes and reports of a hospital review committee); *Mewborn v. Heckler*, 101 F.R.D. 691 (D.D.C. 1984) (denying discovery of peer review materials to plaintiff in a case under the FTCA); *Laws v. Georgetown Univ. Hosp.*, 656 F. Supp. 824 (D.D.C.1987) (finding a letter written by the attending obstetrician to the chairman of the Department of Anesthesiology at defendant hospital privileged as part of a peer review

substantial authority, this court recognizes a qualified privilege for confidential evaluative materials produced by the NIH review process involved here based on the public policy evident in Maryland privilege law, the intent of Congress in passing the Patient Safety Quality Improvement Act of 2005, and the particular circumstances of this case.

1. Maryland Law

This court is persuaded that the policy behind Maryland's medical review committee statute weighs in favor of recognizing a privilege on these facts. The Maryland statute directs that "except as otherwise provided . . . the proceedings, records and files of a medical review committee are not discoverable and are not admissible in evidence in any civil action."[40] A medical review committee is defined as a committee or board that (1) is within one of the categories listed in § 1-401(b) of the Maryland medical review committee statute and (2) performs at least one of the functions listed in § 1-401(c) of the same statute.[41]

The court considers a number of categories listed in § 1-401(b) applicable here. Subsection (b)(1), for example, includes "a regulatory board or agency established by state or federal law to license, certify, or discipline any provider of health care."

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of the attending obstetrician's work); *Doe v. St. Joseph's Hosp. of Fort Wayne*, 113 F.R.D. 677 (N.D. Ind. 1987) (finding Indiana privilege statute applicable to federal civil rights claim brought by plaintiff doctor following peer review and loss of staff privileges); *Weekoty v. United States*, 30 F. Supp. 2d 1343 (D.N.M. 1998) (recognizing a "self-critical analysis" privilege for materials related to hospital morbidity and mortality conferences).

[39] *See Navilar v. Mercy Health System-Western Ohio*, 210 F.R.D. 597, 604 (S.D. Ohio 2002) (collecting cases and stating at 609 that cases reaching the opposite conclusion are "anomalies in the corpus of federal case law").

[40] MD. CODE ANN., HEALTH OCC. § 1-401(d)(1).

[41] MD. CODE ANN., HEALTH OCC. § 1-401(a)(3).

"Provider of health care" is defined in § 1-401(a)(4) as "any person who is licensed by law to provide health care to individuals." Here, the NIH IRBs and DSMBs provide initial approval for and ongoing certification of research trials conducted by providers of health care within the NHLBI. Similarly, subsection (b)(13) includes "[a] Mortality and Quality Review Committee established under § 5-801 or a Morbidity, Mortality, and Quality Review Committee established under § 18-107 of the Heath-General Article." The purpose of a Morbidity and Quality Review Committee is "to prevent avoidable deaths and to improve the quality of care provided to persons with developmental disabilities."[42] The purpose of a Morbidity, Mortality, and Quality Review Committee is to devise and institute means to prevent and control, among other things, infant mortality and diseases of childbirth, infancy, and early childhood.[43] In this case, NIH review bodies functioned to oversee and develop trials concerning obstructive hypertrophic cardiomyopathy–a serious genetic condition with a substantial risk of sudden cardiac death, especially in children. The purpose of the study at issue here was to learn whether providing pacemakers to children with this condition could reduce obstruction and thickening of the heart muscle, as well as improve symptoms and exercise performance as the child grew.[44] Finally, subsection (b)(15) includes "The Maryland Health Care Commission or its staff, when performing the functions listed in [§ 1-401(c) of the Health Occupations Article], provided that the data or medical information under review is furnished to the Maryland Health Care Commission by another medical review

[42] MD. CODE ANN., HEALTH GEN. § 5-802(b).
[43] MD. CODE ANN., HEALTH GEN. § 18-107(a)(1).
[44] D.I. 49-1 at ¶ 7.

committee." The Maryland Health Care Commission is "an independent regulatory agency whose mission is to plan for health system needs, promote informed decision-making, increase accountability, and improve access in a rapidly changing health care environment . . . ."[45] In this case, NIH IRBs are independent committees consisting of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of participants are protected.[46] IRBs are mandated by federal regulation for all institutions in the United States that conduct or support biomedical research involving people, and rely upon information received from DSMBs in discharging their duties.[47] In turn, DSMBs review clinical trial progress, ensure subject safety and data quality, and protect the confidentiality of trial data.[48]

The court also agrees with the United States that NIH review bodies perform a number of functions listed in § 1-401(c) of the Maryland Health Occupations Article, including: (1) evaluating and seeking to improve the quality of heath care; (2) evaluating the need for and the level of performance of health care provided; and (3) evaluating the qualifications, competence, and performance of providers of health care.

The court's finding that NIH review bodies are encompassed by Maryland's medical review committee statute is strengthened by the statute's purpose, i.e., "to foster effective review of medical care and thereby improve the quality of health care."[49]

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[45] The Maryland Health Care Commission, *Home*, *at* http://mhcc.maryland.gov/index.html (last visited May 17, 2010).

[46] *See* D.I. 49-1 at ¶ 9; 45 C.F.R. § 46.103.

[47] *See* 45 C.F.R. § 46.101.

[48] *See* D.I. 49-1 at ¶ 12; NIH Policy for Data and Safety Monitoring (June 10, 1998), *at* http://grants.nih.gov/grants/guide/notice-files/not98-084.html.

[49] *Brem v. DeCarlo, Lyon, Hearn & Pazourek, P.A.*, 162 F.R.D. 94, 97 (D. Md. 1995).

Indeed, the Maryland District Court has noted that "despite Maryland's general rule of interpreting privileges narrowly, the Court of Appeals has stated that the medical review committee statute was intended to provide 'broad statutory protection.'"[50] Nor is Maryland law unique on this point. To wit, all 50 states, as well as the District of Columbia, have created an evidentiary privilege for medical peer review information.[51] These statutes share a common purpose in encouraging physician candidness by eliminating the fear that peer review information will be used against them in subsequent litigation.[52] The same concerns are presented here. The NIH policy for Data and Safety Monitoring, for instance, provides that confidentiality must be maintained during all phases of trials.[53] In addition to safeguarding patient information, this policy is meant to assure "candid and vigorous" oversight without the lingering fear of being dragged into court.[54]

2. The Patient Safety Quality Improvement Act of 2005

Satisfied that the policy behind Maryland's medical review committee statute seeks to foster the review bodies and materials involved here, the court must now ask whether Maryland's privilege can be recognized without substantial cost to federal

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[50] *Id.* at 98 (quoting *Baltimore Sun Co. v. Univ. of Maryland Sys. Corp.*, 584 A.2d 683, 687 (Md. 1991)) (other citations omitted).

[51] Ghazal Sharifi, *Is the Door Open or Closed? Evaluating the Future of the Federal Medical Peer-Review Privilege*, 42 J. Marshall L. Rev. 561, 564 (2009) (citing *Adkins v. Christie*, 488 F.3d 1324, 1330 (11th Cir. 2007), and numerous state statutes).

[52] *See Id.*; *Baltimore Sun*, 584 A.2d at 686 (noting the importance of confidentiality to the peer review process because "physicians are frequently reluctant to participate in peer review evaluations for fear of exposure to liability, entanglement in malpractice litigation, loss of referrals from other doctors, and a variety of other reasons.").

[53] NIH Policy for Data and Safety Monitoring.

[54] *See* D.I. 49-1 at ¶ 12.

substantive and procedural policy. Many courts have looked to the Health Care Quality Improvement Act of 1986 ("HCQIA"), 42 U.S.C. 11101 *et seq.*, in concluding that federal policy is hostile to a medical peer review privilege.[55] The court in *Navilar v. Mercy Health System-Western Ohio* explained the purpose and framework of the HCQIA succintly:

> The HCQIA was enacted in the interest of both reducing medical incompetence and protecting physicians who take part in the peer review process, which ultimately exposes such medical incompetence. In return for requiring "professional review bodies," defined as groups of health care professionals who review the work of their colleagues, to report to the Secretary of Health and Human Services ("Secretary"), among other things, any action taken which adversely affects a physician's clinical privileges, the statute guarantees that all such information "reported under this subchapter [shall be] considered confidential and shall not be disclosed" . . . .[56]

The *Navilar* court agreed with those before it in finding that the HCQIA "carefully crafted a very specific privilege, applicable [only] to peer review material submitted to the Secretary pursuant to the dictates of the mandatory reporting provisions of that statute."[57] Hence, the prevailing analysis of the HCQIA is that "Congress spoke loudly with its silence" in not enacting a broad privilege against discovery of peer review materials.[58]

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[55] *See, e.g., Agster v. Maricopa County*, 422 F.3d 836, 839 (9th Cir. 2005); *Johnson v. Nyack Hosp.*, 169 F.R.D. 550, 560 (S.D.N.Y. 1996); *Robertson v. Neuromedical Ctr.*, 169 F.R.D. 80, 83-84 (M.D. La. 1996); *Syposs v. United States*, 179 F.R.D. 406, 411 (W.D.N.Y. 1998); *Swarthmore Radiation Oncology, Inc. v. Lapes*, No. CIV.A. 92-3055, 1993 WL 517722, at *2-4 (E.D. Pa. Dec. 1, 1993); *Tucker v. U.S.*, 143 F. Supp. 2d 619, 626-28 (S.D. W. Va. 2001).

[56] *Navilar v. Mercy Health System-Western Ohio* , 210 F.R.D. 597, 602 (S.D. Ohio 2002) (citations omitted, brackets in original).

[57] *Id.*

[58] *Teasdale v. Marin Gen. Hosp.*, 138 F.R.D. 691, 694 (N.D. Cal. 1991); *see also Syposs*, 179 F.R.D. at 412 ("Whether the public interest would be served by a medical

While this court does not dispute the majority analysis of the HCQIA, that legislation no longer represents Congress' final word on the issue of medical peer review. The Patient Safety Quality Improvement Act of 2005 ("PSQIA"),[59] which postdates those cases turning on the HCQIA, announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein. In contrast to the HCQIA, which was motivated by the particular need "to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance,"[60] the PSQIA tackled the larger problem of systemic weaknesses in the delivery of health care resulting in preventable adverse events:

> Much of the impetus for this legislation can be traced to the publication of the landmark report, "To Err is Human," by the Institute of Medicine in 1999 (Report). The Report cited studies that found that at least 44,000 people and potentially as many as 98,000 people die in U.S. hospitals each year as a result of preventable medical errors. Based on these studies and others, the Report estimated that the total national costs of preventable adverse events . . . to be between $17 billion and $29 billion, of which health care costs represent one-half. One of the main conclusions was that the majority of medical errors do not result from individual recklessness or the actions of a particular group; rather, most errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent adverse events.[61]

In a 2003 report on the PSQIA, the Senate declared its intent to remedy this situation by

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peer review privilege in federal cases requires a weighing of interests more appropriate for Congress than for the courts."); *Agster*, 422 F.3d at 839 ("As Congress has twice [after amendment in 1987] had occasion and opportunity to consider the privilege and not granted it either explicitly or by implication, there exists a general objection to our doing so.").

[59] 42 U.S.C. § 299b-21 *et seq*.

[60] 42 U.S.C. § 11101(2).

[61] Patient Safety and Quality Improvement; Notice of Proposed Rulemaking, 73 Fed. Reg. 8112, 8112-13 (Feb. 12, 2008).

promoting "a learning environment that is needed to move beyond the existing culture of blame and punishment that suppresses information about health care errors to a 'culture of safety' that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors."[62] The PSQIA was thus designed to encourage this "culture of safety" by "providing for broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety."[63]

The text of the PSQIA corroborates this shift in congressional policy. While the HCQIA applies only to peer review actions affecting individual physicians,[64] the PSQIA protects all "patient safety work product,"[65] a term defined expansively to include any data, reports, records, memoranda, analyses, or written or oral statements which: (1) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; (2) are developed by a patient safety organization for the conduct of patient safety activities and which could result in

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[62] S. Rep. No. 108-196, at *2 (2003).

[63] S. Rep. No. 108-196, at *3 (2003).

[64] *See* 42 U.S.C. § 11137(b) ("Information reported under this subchapter is considered confidential and shall not be disclosed."); 42 U.S.C. § 11133 (requiring health care entities to report information regarding any professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days); 42 U.S.C. § 11151(9) (defining "professional review action" as "an action or recommendation of a professional review body . . . which is based on the competence or professional conduct of an individual physician . . . and which affects (or may affect) adversely the clinical privileges, or membership in a professional society, of the physician").

[65] *See* 42 U.S.C. § 299b-22(a) (providing that, subject to certain exceptions, "patient safety work product shall be privileged and shall not be . . . subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding . . . .").

improved patient safety, health care quality, or health care outcomes; or (3) identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.[66] A "patient safety evaluation system" is defined as "the collection, management, or analysis of information for reporting to or by a patient safety organization."[67] Patient safety organizations ("PSOs") include all organizations that collect and analyze patient safety work product and provide feedback to providers on strategies to improve patient safety and quality of care, and that have been listed by the Department of Health and Human Services as such.[68] Finally, "patient safety activities" are defined to include, *inter alia*: (1) efforts to improve patient safety and the quality of health care delivery; (2) the collection and analysis of patient safety work product; (3) the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices; and (4) the utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.[69]

Whether or not the NIH review bodies at issue here meet the technical requirements for listing as PSOs, they clearly perform the same functions Congress intended the PSQIA to encourage. DSMBs, for example, are composed of experts in all scientific disciplines needed to interpret trial data and ensure participant safety, including clinical trial experts, biostatisticians, bioethicists, and clinicians knowledgeable

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[66] *See* 42 U.S.C. § 299b-21(7).
[67] 42 U.S.C. § 299b-21(6).
[68] *See* S. Rep. No. 108-196, at *5 (2003).
[69] 42 U.S.C. § 299b-21(5).

about the disease and treatment under study.[70] This monitoring and oversight is accomplished by, among other things, reviewing the initial research protocol and plans for data safety and monitoring, performing periodic assessments of data quality and timeliness, evaluating the balance between participant risk and benefit, analyzing the performance of trial sites, and protecting the confidentiality of trial data and results of monitoring.[71] Based on this activity, DSMBs provide IRBs with regular reports and recommendations concerning continuation or conclusion of trials. In addition to responding to these recommendations, IRBs provide oversight of the DSMB and the trial itself, ensuring that DSMB monitoring is timely and effective as well as that those responsible for monitoring are free from conflicts and possess the necessary expertise to function properly.[72] IRBs are also provided feedback on a regular basis, including findings from adverse event reports.[73] IRBs use this information to determine whether to provide initial and ongoing approval for a trial. Notably, IRBs are authorized to suspend, modify, or terminate approval of trials that have been associated with unexpected serious harm to subjects, or that are not being conducted in accordance federal regulation or with the IRB's prior decisions, conditions, and requirements.[74] The NIH review process, then, collects the same kind of safety data as enumerated in the PSQIA, within the same organizational structure, to accomplish the same goal (i.e., ensuring participant safety and effectiveness of care). The court is confident that

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[70] *See* NIH Policy for Data and Safety Monitoring.
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] *See* Sheet 12–NIH Institutional Review Board Administrative Procedures (Dec. 5, 2006), *at* http://ohsr.od.nih.gov/info/sheet12.html.

protecting otherwise confidential and evaluative materials resulting from this process would not substantially offend the federal policy announced in the PSQIA.

3. The Facts of This Case

This finding, however, does not end the inquiry. The court must also consider the particular facts of this case to ensure that no other federal policy is offended by protecting confidential and evaluative NIH review materials from disclosure. The court discerns no such offense here. Unlike claims alleging violation of federal civil rights (which implicate the strong federal policy of rooting out invidious discrimination) or anti-trust laws (which involve the equally vital purpose of eradicating anticompetitive business practices), no such federal policy is at stake in a medical malpractice case.[75] While there is certainly a public benefit in reducing malpractice and identifying incompetent doctors, the injury in a malpractice action is typically personal to the plaintiff and not representative of any larger societal harm.

Nor is the plaintiff's ability to build his case unnecessarily impeded here. Although courts are understandably reluctant to recognize a privilege in claims based upon abuse of the review process itself (where a privilege would leave plaintiffs without access to the best, if not the only, evidence of wrongdoing),[76] in a medical malpractice

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[75] *See Mem'l Hosp. for McHenry County v. Shadur*, 664 F.2d 1058, 1061 (7th Cir. 1981) ("The public interest in private enforcement of federal antitrust law in this context is simply too strong to permit the exclusion of relevant and possibly crucial evidence by application of the Hospital's privilege."); *Virmani v. Novant Health Inc.*, 259 F.3d 284, 289 (4th Cir. 2001) ("The interest in facilitating the eradication of discrimination by providing perhaps the only evidence that can establish its occurrence outweighs the interest in promoting candor in the medical peer review process.") (citing *Univ. of Pa. v. EEOC*, 493 U.S. 182, 193 (1990) ("[F]erreting out . . . invidious discrimination is a great, if not compelling, governmental interest.").

[76] *See Shadur*, 664 F.2d at 1062 (reasoning in an antitrust action that "to recognize hospital review or disciplinary proceedings as privileged in the context of a

case the critical events occur outside the deliberations of the review board, and generate evidence that this court, following state and federal privilege laws, will not protect from disclosure.[77] While there is some evidentiary benefit in obtaining a review board's evaluations of relevant evidence, nothing prevents this plaintiff from procuring his own experts and obtaining such evaluations for himself.

Finally, the court should clarify that the privilege recognized today applies only to those materials prepared with the expectation that they would be kept confidential and not in fact disclosed.[78] The NIH review process is complex, providing for both public and private review of trial data.[79] Obviously, records and materials from meetings or

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malpractice action will generally have little impact upon the plaintiff's ability to prove a meritorious claim. . . . The same cannot be said . . . where the plaintiff's claim arises out of the disciplinary proceedings themselves and not some event or occurrence that exists independently of those proceedings."); *Virmani*, 259 F.3d at 291 (applying the same logic in an employment discrimination claim); *Adkins v. Christie*, 488 F.3d 1324, 1329-30 (11th Cir. 2007) (following *Virmani*).

[77] *See*, *e.g.*, PSQIA, 42 U.S.C. § 299b-21(7)(B) (clarifying that original patient and provider records as well as information collected, maintained, developed, or existing separately from a patient safety evaluation system do not constitute patient safety work product); MD. CODE ANN., HEALTH OCC. § 1-401(e) (providing that the privilege does not apply to any record or document that is considered by the medical review committee and that otherwise would be subject to discovery and introduction into evidence in a civil trial).

[78] *See Dowling v. Am. Haw. Cruises, Inc.*, 971 F.2d 423, 425-26 (9th Cir. 1992) (stating that the expectation of confidentiality and the actual preservation of that confidentiality is a "general proviso" within the law of privileges) (citing James F. Flanagan, *Rejecting a General Privilege for Self-Critical Analyses*, 51 Geo. Wash. L. Rev. 551, 574-76 (1983); 8 J. WIGMORE, WIGMORE ON EVIDENCE § 2285, at 527 (1961); *Peterson v. Chesapeake & Ohio Ry.*, 112 F.R.D. 360, 363 (W.D. Mich. 1986) (refusing to apply the privilege to investigative report because report was not "performed with the expectation that the analysis [would] remain confidential" and in fact had not been kept confidential); *Westmoreland v. CBS*, Inc., 97 F.R.D. 703, 706 (S.D.N.Y.1983) (same)).

[79] *See* Sheet 12–NIH Institutional Review Board Administrative Procedures (stating that IRB meetings are open to the public except for those discussions the Chair determines deal with private or confidential information); NIH Policy for Data and Safety Monitoring (noting that DSMBs meet first in open session, followed by a closed session in which members review emerging trial data).

reviews held open to the public or later made publicly available will not be protected here.

IV. CONCLUSION

For the reasons stated above, the court recognizes a qualified privilege for confidential and evaluative materials produced by the NIH review process in this case. Therefore, IT IS ORDERED that:

1. The United States' Motion for Protective Order (D.I. 48) is GRANTED in part and DENIED in part;
2. Consistent with this memorandum order, the United States shall produce, on or before June 22, 2010, all nonconfidential and/or nonevaluative documents relating to the NIH peer review process;
3. To the extent any such document contains both privileged and nonprivileged information, the United States shall produce that document with privileged information redacted;

4. On or before June 22, 2010, the United States shall produce amended privilege logs reflecting any modifications resulting from compliance with this order.

Date: May 25, 2010

/s/ Mary Pat Thynge
United States Magistrate Judge